REMARKS

Claims 1, 2, 4-10 and 13-14 are pending in the present application. Claim 3 is canceled. Claims 11-12 were previously canceled. Claims 1, 2, 4-5 and 13 are amended. Support for amended claim 1 is found on page 4 at line 29 and original claim 3. Claim 2 is amended in accordance with amended claim 1 to recite proper antecedent basis. Claim 4 is amended to remove dependency from a canceled claim. Support for claim 5 is found on page 4 at line 29 and original claim 1. Support for claim 13 is found on page 4 at line 29 and page 14, lines 13-22. No new matter is added by way of these amendments.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-10, 13 and 14 are rejected under 35 USC §112, second paragraph, as being indefinite. Applicants respectfully traverse.

Specifically, the Examiner states that step a) does not clarify the elements that comprise the immune agglutination reaction and the agglutinated insoluble carrier particles. Additionally, the Examiner asserts that step d) is unclear because it does not clarify how the counted agglutinated insoluble carrier particles provide an assay for a target antibody or a target antigen.

Step a) of claim 1 is amended to recite, "mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the target antibody or an antibody against the target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles." Step d) is amended to recite "distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered light detected in the step (b), in reference to the first and second threshold values set in the step (c), so as to obtain the concentration of the target antigen or the target antibody present in the whole

blood sample based on the number of agglutinated insoluble carrier particles and the unagglutinated insoluble carrier particles."

Because a skilled artisan understands from claim 1 which elements comprise the immune agglutination reaction and which elements comprise the agglutinated insoluble carrier particles, as well as how the particles are used in the claimed target antigen or target antibody assay, claim 1 is not indefinite. Likewise, claims 2 and 4-10, which depend from claim 1 and incorporate the language of claim 1 are not indefinite. Claim 3 is canceled. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Additionally, the Examiner asserts that claim 13 is indefinite for recitation of the phrase "dispensing means." Claim 13 is amended to recite "dispenser." Likewise, claim 14, which depends from claim 13 and incorporates the term "dispenser" is not indefinite. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim Rejections under 35 USC §102

The '714 reference

Claims 13-14 are rejected under 35 USC §102(b) as being anticipated by US Patent No. 5,527,714 to Kosako ("'714"). Applicants respectfully traverse.

The Present Invention

The present invention is drawn to an immunoassay apparatus for assaying a target antigen or a target antibody present in a whole blood sample, comprising a reaction part for mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the target antibody or an antibody against the target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles; a dispenser for introducing the resulting immune

agglutination reaction mixture to a flow cell, a laser for irradiating the particles passing through the flow cell with laser light, a photo acceptance unit for detecting scattered light generated thereby, signal processing means for converting the scattered light to an electrical signal, and data processing means for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to the signal based on intensity of the scattered light; for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values; for obtaining the concentration of the target antigen or the target antibody present in the whole blood sample based on the number of agglutinated insoluble carrier particles and the unagglutinated insoluble carrier particles; and for correcting the concentration of the target antigen or the target antibody according to the number of the blood cells.

The '174 reference

In contrast, the '174 reference discloses an apparatus for preparing a corrected size distribution of desired particles in a sample. The apparatus comprises a flow cell having a mixing or agitating part to mix an agglutination reaction mixture, a dispenser, a laser, a detector for detecting scattered light, a signal processing means and a calculating means. The '174 reference, however, fails to disclose, *inter alia*, the "data processing means" as recited in claim 13.

In order to anticipate a claim, each and every element must be disclosed in the reference. The '174 reference does not disclose data processing means wherein " a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells", is determined. Additionally, the '174 reference fails to disclose a data processing means capable of "distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values."

Moreover, the '174 reference does not teach an apparatus wherein blood cells are counted. Thus, the '174 reference fails to disclose a data processing means for "correcting the concentration of the target antigen or the target antibody according to the number of the blood cells."

Because the '174 reference fails to disclose the element of a "data processing means for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to the signal based on intensity of the scattered light; for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values; for obtaining the concentration of the target antigen or the target antibody present in the whole blood sample based on the number of agglutinated insoluble carrier particles and the unagglutinated insoluble carrier particles"; and the element of "correcting the concentration of the target antigen or the target antibody according to the number of the blood cells", the '174 reference fails to anticipate claim 13. Likewise, claim 14, which depends from claim 13 and incorporates all of the elements thereof, is not anticipated by the '174 reference, at least by virtue of dependency. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Claim Rejections under 35 USC §103

Claims 1-4 and 9-10

Claims 1-4 and 9-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '174 reference in view of US 2001/0046685 to Moskowitz *et al.* ("Moskowitz"). Applicants respectfully traverse.

The combination of the '174 reference and the Moskowitz reference fails to disclose, teach or suggest all of the elements of claim 1. The '174 reference teaches a method for

preparing a corrected distribution of desired particles in an analyte by detecting particles in the analyte and then determining a total distribution of particle sizes and a distribution of spurious particle sizes. The corrected distribution of desired particles is then calculated by subtracting the distribution of spurious particle sizes from the total distribution of sizes. However, the '174 reference fails to disclose, teach or suggest, *inter alia*, "a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells" and "distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values." Moreover, the the '174 reference does not disclose, teach or suggest that blood cells are counted. Thus, the reference also fails to disclose, teach or suggest "correcting the concentration of the target antigen or the target antibody according to the number of the blood cells."

Thus, the '174 reference fails to teach or suggest step c), step d) or step e) of claim 1 which recite "(c) setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to intensity of the scattered light", " (d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered light detected in the step (b), in reference to the first and second threshold values set in the step (c), so as to obtain the concentration of the target antigen or the target antibody present in the whole blood sample based on the number of agglutinated insoluble carrier particles and the unagglutinated insoluble carrier particles", and "(e) correcting the concentration of the target antigen or target antibody according to the number of the blood cells."

Likewise, the Moskowitz reference alone or in combination with the '174 reference fails to teach or suggest these elements. The Moskowitz reference teaches "a composition comprising an aqueous medium, a reagent for assessing fibrinogen biological activity and a reagent for assessing the activity of a reagent used for determining platelet count", as well as "a method for conducting a control for an assay for platelet function activity and a control for the platelet count

assay." (See, Moskowitz abstract). Thus, the Moskowitz reference fails to disclose, teach or suggest, *inter alia*, steps (c) and (d) of claim 1. Furthermore, the Moskowitz references does not disclose, teach or suggest "correcting the concentration of the target antigen or target antibody according to the number of blood cells", as recited in step e) of claim 1. Therefore, neither the Moskowitz reference, the '174 reference, nor the combination thereof, teach or suggest steps (c), (d) or (e) of claim 1.

In order to establish a *prima facie* case of obviousness, the combination of references must teach or suggest all of the elements of the claim. Because the combination of the '174 reference and the Moskowitz reference fails to teach or suggest all of the elements of claim 1, claim 1 is not obvious over the '174 reference in view of Moskowitz. Likewise, claims 2, 4 and 9-10, which incorporate the elements of claim 1 are allowable, at least by virtue of dependency. Claim 3 is canceled. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Claim 8

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the '174 reference in view of Moskowitz *et al.* and further in view of WO 98/20351 to Steel *et al.* ("Steel"). Applicants respectfully traverse.

As discussed *supra*, neither the '174 reference, the Moskowitz reference, nor the combination thereof, teaches or suggests steps (c), (d) or (e) of independent claim 1. Likewise, the Steel reference fails to teach or suggest these elements. Because claim 8 depends on claim 1 and incorporates all of the elements thereof, claim 8 is not obvious over the combination of the '174 reference, the Moskowitz reference and the Steel reference. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: AUG - 7 2006

Respectfully submitted,

#28977

By
Marc S. Weiner
Registration No.: 32,181
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant